Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

HL

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/588,637	01/19/96	BARBOUR	

EXAMINER	
RYAN, V	1641

ART UNIT	PAPER NUMBER
1641	15

020999
FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE
NEW YORK NY 10151

HM12/0707

DATE MAILED: 07/07/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2/25/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-4, 6-10, 12, 13 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-4, 6-10, 12, 13 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

DETAILED ACTION

Continued Prosecution Application

The request filed on February 25, 1999 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/588,637 is acceptable and a CPA has been established. An action on the CPA follows.

The text of those sections of U.S. Code not included in this Office Action can be found in a prior Office Action.

The Examiner acknowledges receipt of the amendment filed February 25, 1999.

In this application:

Claim 5 was canceled.

Claim 13 was added.

Claims 1-4, 6-10, 12 and 13 are now pending and under examination.

Response to Amendment

(1) The objection to the drawings under 37 CFR 1.84 or 1.152 for the reasons stated on PTO 948.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-10, 12 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 7 of U.S. Patent No. 5,688,512. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is directed to a method for inducing an immunological response in a mammalian host susceptible to Lyme disease or *Borrelia burgdorferi* infection comprising "mucosally" administering substantially pure OspA. US PAT 5,688,512 claims a method of inducing a protective immunological response against *Borrelia burgdorferi* in an animal or human susceptible to Lyme

disease comprising administering a vaccine comprising substantially pure OspA.

Effective June 8, 1995, any continuing application of a previously filed application will expire twenty years from the filing date of the earlier case. A terminal disclaimer is still required to overcome a nonstatutory double patenting rejection in a continuing application, even though both patents would expire on the same day anyway because of the twenty-year-term provisions under GATT/NAFTA. The reason is that the enforceability/common ownership provision of a terminal disclaimer under 37 CFR 1.32(C)(3) remains. A terminal disclaimer includes a provision that the later filed application which matures into a patent shall only be enforceable as long as the earlier and later filed patents are commonly owned. If and when the patents cease to be commonly owned, the patent containing the terminal disclaimer does not expire, but it becomes unenforceable. This would avoid the problem of an alleged infringer being harassed by two different parties with patents covering the same patentable invention (as defined in 37 CFR 1.601(n)).

Claims 1-4, 6-10, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergstrom et al (US 5,688,512).

Claim Rejections - 35 USC § 112

Claims 1-4, 6-10, 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation of "substantially pure". "Substantially" is a broad term (See In re Nehrenberg (CCPA) 126 USPQ 383. It is unclear what is encompassed by the term "substantially pure".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-10, 12 and 13 are rejected under 35 U.S.C. 103 as being unpatentable by Burgess.

Burgess, EC (Annals New York Academy of Sciences, Vol 539. 1988. pages 235-243) teaches a method of orally administering *Borrelia burgdorferi* to animals. (See especially pages 236-237). The *Borrelia burgdorferi* organisms were identified by using a monoclonal antibody (H5532) which is specific for OspA. Furthermore, the composition elicited antibodies in mice. (See especially page 239)

Although the OspA of the prior art was not obtained by the method recited in the claims, the source of a particular protein does not impart novelty or unobviousness to the protein when said protein is taught by the prior art, absent evidence to the contrary or unexpected results.

Given the teachings of the prior art that a composition comprised of *Borrelia burgdorferi* which was identified by the monoclonal antibody specific to OspA produced antibodies when administered orally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to mucosally administer the composition comprised of OspA with a reasonable expectation of producing antibodies.

The Group and/or Art Unit location of your application in the Patent and Trademark Office may have changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1641.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to V. Ryan whose telephone number is (703)305-6558.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Papers related to this application may be submitted to the Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax number for Art Unit 1641 is (703)308-4242.

V. Ryan
Patent Examiner/Art Unit 1641
July 1999
Ryan/vr

James C. Housel 7/6/99
JAMES C. HOUSEL
SUPERVISORY PATENT EXAMINER